UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

EAGLE PHARMACEUTICALS, INC., and SCINOPHARM TAIWAN, LTD. Plaintiffs, v. SHILPA MEDICARE LIMITED, Defendant.	Civil Action No. _____

COMPLAINT

Plaintiffs Eagle Pharmaceuticals, Inc. ("Eagle") and ScinoPharm Taiwan Ltd. ("ScinoPharm") (collectively "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendant Shilpa Medicare Limited ("Shilpa" or "Defendant") hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Patent Laws of the United States, Title 35 of the United States Code, arising from Defendant's submission of New Drug Application ("NDA") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell its Pemetrexed Injection, 100 mg/10 mL, 500 mg/50 mL and 1 g/100 mL ("the Shilpa NDA Products") prior to the expiration of U.S. Patent No. 9,604,990 ("the '990 Patent").

THE PARTIES

2. Plaintiff Eagle is a corporation organized and existing under the laws of Delaware, having its corporate offices and principal place of business at 50 Tice Boulevard, Suite 315, Woodcliff Lake, New Jersey 07677.

3. Plaintiff ScinoPharm Taiwan Ltd. is a foreign corporation organized and existing under the laws of Taiwan, having corporate offices at No. 1 Nan-Ke 8th Road, Southern Taiwan Science Park, Shan-Hua Tainan 74144, Taiwan.

4. Upon information and belief, defendant Shilpa Medicare Limited is a corporation organized and existing under the laws of the Republic of India, having a principal place of business at 12-6-214/Al, Hyderabad Road, Raichur-584 135, Karnataka, India.

5. On information and belief, defendant Shilpa is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, distributing, and/or importing pharmaceutical products into and throughout the United States, including the State of New Jersey.

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq*., including 35 U.S.C. § 271(e)(2).

7. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b). Shilpa is a foreign corporation not residing in any United States district and may be sued in any judicial district. 28 U.S.C. § 1391(c).

9. On information and belief, Shilpa develops, manufactures, and/or distributes drug products for sale and use throughout the United States, including in this judicial district.

10. This Court has personal jurisdiction over Shilpa because, *inter alia*, Shilpa, on information and belief: (1) intends to market, sell, or distribute Shilpa's NDA Product to residents of this State; (2) makes its pharmaceutical products available in this State; and (3) enjoys substantial income from sales of its pharmaceutical products in this State.

11. Additionally, on information and belief, Shilpa has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See, e.g.*, *Eisai R&D Management Co., Ltd. et al v. Shilpa Medicare Limited*, No. 3:20-cv-06729 (D.N.J.); *Eisai R&D Management Co., Ltd. et al v. Shilpa Medicare Limited*, No. 3:19-cv-19998 (D.N.J.); *Celgene Corporation v. Shilpa Medicare Ltd.*, No. 3:18-cv-11157 (D.N.J.).

12. Alternatively, to the extent the above facts do not establish personal jurisdiction over Shilpa, this Court may exercise jurisdiction over Shilpa pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Shilpa would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Shilpa has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Shilpa satisfies due process.

BACKGROUND

U.S. Patent No. 9,604,990

13. On March 28, 2017, the PTO duly and legally issued United States Patent No. 9,604,990 ("the '990 Patent") entitled "Crystalline forms of pemetrexed diacid and manufacturing processes therefor" to inventors Ying-Tzu Lin, Kuan-Hsun Wang, Wei-Shuo Lo, Wen-Wei Lin, and Wan-Yin Cheng. A true and correct copy of the '990 Patent is attached as Exhibit 1.

14. The '990 patent is assigned to ScinoPharm.

15. Eagle is an exclusive licensee of the '990 patent.

PEMFEXY ®

16. Eagle is the holder of NDA No. 209472 ("the Eagle NDA") for pemetrexed solution 25 mg/mL, which is sold under the trade name PEMFEXY®.

17. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '990 Patent is listed in the Orange Book with respect to PEMFEXY® in the 500 mg/20 mL (25 mg/mL) dosage.

18. The '990 Patent covers the PEMFEXY® product.

ACTS GIVING RISE TO THIS ACTION

COUNT I - INFRINGEMENT OF THE '990 PATENT

19. Plaintiffs reallege paragraphs 1-18 as if fully set forth herein.

20. On information and belief, Shilpa submitted NDA No. 215179 ("the Shilpa NDA") to the FDA, pursuant to 21 U.S.C. § 355(b), seeking approval to market its pemetrexed injection, in 100 mg/10 mL, 500 mg/50 mL, and 1 g/100 mL ("the Shilpa NDA Products").

21. Shilpa's NDA No. 215179 refers to and relies upon the Eagle NDA for PEMFEXY® as a reference listed drug.

22. Plaintiffs received a letter from Shilpa ("the Shilpa Notice Letter"), stating that Shilpa had included a certification in the Shilpa NDA, pursuant to 21 U.S.C. § 355(b)(3)(D), stating that, *inter alia*, certain claims of the '990 Patent are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Shilpa's NDA Products ("the Shilpa Paragraph IV Certification"). In the Shilpa Notice Letter, Shilpa did not assert that the '990 Patent is invalid.

23. This action is being filed within 45 days of Plaintiffs' receipt of Shilpa's Notice Letter.

24. Shilpa has infringed at least one claim of the '990 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Shilpa NDA, by which Shilpa seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, and/or importation of the Shilpa NDA Products prior to the expiration of the '990 Patent.

25. Shilpa has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Shilpa NDA Products in the event that the FDA approves the Shilpa NDA. Accordingly, an actual and immediate controversy exists regarding Shilpa's infringement of the '990 Patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

26. On information and belief, Shilpa's manufacture, use, offer to sell, or sale of the Shilpa NDA Products in the United States or importation of the Shilpa NDA Product into the United States during the term of the '990 Patent would further infringe at least one claim of the '990 Patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

27. On information and belief, the Shilpa NDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '990 Patent either literally or under the doctrine of equivalents.

28. On information and belief, the use of the Shilpa NDA Products constitutes a material part of at least one of the claims of the '990 Patent; Shilpa knows that its NDA Products are especially made or adapted for use in infringing at least one of the claims of the '990 Patent, either literally or under the doctrine of equivalents; and its NDA Products are not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

29. On information and belief, the offering to sell, sale, and/or importation of the Shilpa NDA Products would contributorily infringe at least one of the claims of the '990 Patent, either literally or under the doctrine of equivalents.

30. On information and belief, Shilpa had knowledge of the '990 Patent and, by its promotional activities and package inserts for its NDA Products, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '990 Patent, either literally or under the doctrine of equivalents.

31. On information and belief, the offering to sell, sale, and/or importation of the Shilpa NDA Products would actively induce infringement of at least one of the claims of the '990 Patent, either literally or under the doctrine of equivalents.

32. Plaintiffs will be substantially and irreparably harmed if Shilpa is not enjoined from infringing the '990 Patent.

33. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorney fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment against Shilpa and for the following relief:

a. A Judgment be entered that Shilpa has infringed at least one claim of the '990 Patent by submitting the Shilpa NDA;

b. A Judgment be entered that this case is exceptional, and that Plaintiffs are entitled to its reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

c. That Shilpa, its officers, agents, servants, employees, and those persons acting in active concert or participation with it be preliminarily and permanently enjoined from: (i) engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs or methods of administering drugs claimed in the '990 Patent, and (ii) seeking, obtaining or maintaining approval of the Shilpa NDA until the expiration of the '990 Patent or such other later time as the Court may determine;

d. A judgment ordering that the effective date of any FDA approval for Shilpa to make, use, offer for sale, sell, market, distribute, or import Shilpa's NDA Product, or any product the use of

which infringed the '990 Patent, be not earlier than the expiration date of the '990 Patent, inclusive of any extension(s) and additional period(s) of exclusivity;

e. That Plaintiffs be awarded monetary relief if Shilpa commercially uses, offers to sell, or sells its proposed NDA Product or any other product that infringes or induces or contributes to the infringement of the '990 Patent, within the United States, prior to the expiration of that patent, including any extensions, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest;

f. Costs and expenses in this action; and

g. Such other and further relief as the Court deems just and appropriate.

Dated: December 23, 2020

Respectfully submitted,

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding, except that the New Drug Application ("NDA") submitted by Defendant Shilpa Medicare Limited ("Shilpa") to the Food and Drug Administration that is at issue in this matter is also at issue in *Eli Lilly and Company v. Shilpa Medicare Limited*, 1-20-cv-03132 (S.D. Ind. Dec. 4, 2020) (involving a different patent, U.S. Patent No. 7,772,209).

Dated: December 23, 2020

Respectfully submitted,

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CERTIFICATION PURSUANT TO L. CIV. R. 201.1

I hereby certify that, to the best of my knowledge, the matter in controversy is not subject to compulsory arbitration in that Plaintiffs seek, *inter alia*, injunctive relief.

Dated: December 23, 2020

Respectfully submitted,

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